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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,936	11/20/2003	Tod R. Smeal	034536-0220	6791

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EXAMINER	
AEDER, SEAN E	

ART UNIT	PAPER NUMBER
1642	

MAIL DATE	DELIVERY MODE
05/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/716,936	SMEAL ET AL.	
	Examiner	Art Unit	
	Sean E. Aeder, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 18-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15 and 18-25* is/are rejected.

7)☒ Claim(s) *15* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Request for Continued Examination

The request filed on 3/6/07 for a Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 10/716936 is acceptable and a RCE has been established. An action on the RCE follows.

Claims 1-15 and 18-25 are pending and are currently under consideration.

The following Office Action contains New Rejections.

Rejections Withdrawn

The rejection of claims 1-15 and 18-25 under 35 U.S.C., first paragraph, is withdrawn. However, it is noted that a new rejection under 35 U.S.C., first paragraph, is set-forth below.

New Objection

Claim 15 is objected to for failing to further limit the claim from which it depends. Claim 15 recites: "The method of claim 1, wherein the therapeutic composition directly or indirectly decreases the phosphorylation of PAK4". Since claim 1 recites "...wherein a lower level of PAK4 phosphorylation on ser-474 in the subsequent biopsy compared to the first biopsy indicates that the therapeutic composition decreases PAK4 phosphorylation on ser-474 in the mammal...", it is unclear how said decrease in phosphorylation of PAK4 could occur in any manner other than directly or indirectly from the therapeutic composition. Proper correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-15 and 18-25 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

Claims 1-15 and 18-25 are drawn to a method for monitoring the effect of a therapeutic composition comprising monitoring ser-474 phosphorylation in biopsies before and after treatments with a therapeutic composition, wherein a lower level of PAK4 phosphorylation on ser-474 after said treatments, as compared to the level of PAK4 phosphorylation on ser-474 before said treatments, indicates that the therapeutic composition decreases PAK4 phosphorylation on ser-474.

The specification teaches a phosphospecific anti-PAK4 polyclonal antibody, #108, which was raised against a fragment of PAK4 that was phosphorylated on serine-474 (paragraph 52, in particular). The specification further states that phosphospecific antibodies directed against serine-474 detect activated PAK4 (paragraph 4). The specification further states that "The data for the phosphospecific antibody (#108) in colon carcinomas is especially informative (6 out of 6 patients showed marked perinuclear staining in tumor and not distal benign tissue....This result strongly suggests that PAK4 is specifically active in colon tumor cells and inactive in benign colon tissue from the same patient. Staining of phosphorylated PAK4 was also observed in renal cell carcinoma, lung adenocarcinoma, prostatic adenocarcinoma, intraductal breast

adenocarcinoma, and ovarian adenocarcinoma" (paragraph 80). The specification further states: "In tumors, strong staining with phosphospecific-PAK4 antibody was identified in colonic adenocarcinomas (while distal benign tissue failed to show phospho-PAK4 staining). On a scale of 0-3, "0" indicates no staining, "1" is indicative of weak staining, "2" indicates moderate staining and "3" indicates strong staining. Adenomatous epithelium was faintly to moderately positive, but most normal epithelium showed only staining of "1" for phosphorylated PAK4. Prostatic adenocarcinoma showed moderate staining ("2")" (paragraph 81). The specification further states: "In benign tissues, the most prominent staining for phosphorylated PAK4 was seen in adeipocytes, cardiac myocytes, sebaceous glands, and occasional macrophages. Additional positive cell and tissue types included hair follicles, benign prostatic epithelium, breast epithelium, and urothelium" (paragraph 82). Though the data are not explicitly shown, the specification suggests that phosphorylation of PAK4 on ser-474 is indicative of colon carcinoma, where phosphorylation of PAK4 is described as being found in tumor and not in distal benign tissue (paragraph 80, in particular).

Further, the specification provides no working examples demonstrating that a decrease in PAK4 phosphorylation on ser-474 is indicative of any therapeutic effect. The specification only provides general guidelines or prophetic teaching of how changes in PAK phosphorylation levels *could* be used to monitor an undisclosed effect of a therapeutic composition (paragraph 9, in particular).

Following the requirements of the Utility Guidelines, (<http://www.uspto.gov/web/offices/pac/utility/utilityguide.pdf>), "substantial utility" is a

utility that defines "real world use", wherein utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. In the instant case, the claimed method is not a "real world" utility. The claimed method of detecting a decrease in a phosphorylation of a residue in response to a therapeutic, wherein said decrease is not indicative of anything but a decrease in phosphorylation of said residue, is not a "real world" use.

Section 101 requires a utility that is both substantial and specific. See In re Fisher, 421 F.3d 1365, 1371, 76 USPQ 1225, 1229 (Fed. Cir. 2005). The Fisher court held that disclosing a substantial utility means "show[ing] that an invention is useful to the public as disclosed in its current form, not that that it may prove useful to the public some future date after further research. Simply put, to satisfy the 'substantial' utility requirement, an asserted use must show that the claimed invention has a significant and presently available benefit to the public." Id., 76 USPQ2d at 1230. In the instant case, a method of detecting a decrease in a phosphorylation of a residue in response to a therapeutic, wherein said decrease is not indicative of anything but a decrease in phosphorylation of said residue, is not a significant and presently available benefit to the public. Thus, the claimed method does not have a "substantial" utility.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-15 and 18-25 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility and a substantial utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know *how to perform* the claimed invention.

Summary

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SEA

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